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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,464

01/16/2007

Rasappa G. Arumugham

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11/10/2011

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EXAMINER

SNYDER, STUART

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

11/10/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,464	ARUMUGHAM ET AL.	
	Examiner	Art Unit	
	STUART W. SNYDER	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 384, 386, 387, 392, 394-396 and 402 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 384, 386-387, 392, 394-396, and 402 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/6/2011; 7/27/2011</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/6/2011 has been entered.

Status of the Claims

2. Claims 384, 386-387, 392, 394-396 and 402 are pending and examined herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 384, 386-387, 392, 394-396 and 402 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mariotti, et al. in view of Conley, et al. and Joyce, et al. The claims are drawn to compositions comprising, *inter alia*, a conjugate comprising a CRM197 and an immunogenic peptide wherein unreacted crosslinking agents on CRM197 are capped. The relevance of Mariotti, et al. in view of Conley, et al. was discussed in a previous Office Action (mailed 12/30/2009) and is essentially that heterologous, immunogenic peptides were

conjugated to CRM197 (Mariotti, et al.) whereas capping of unreacted crosslinking agents are capped on conjugates of an OMPC (Conley, et al.). Applicants traverse the obviousness of combination of the methods by arguing that optimization of novel methods is not obvious. Under ordinary conditions, a skilled artisan would have recognized that unreacted crosslinking agents have the potential to crosslink with undesired elements within solutions containing such; the simplest such unwanted reaction would be the multimerization of conjugates themselves or other proteins in immune solutions that may serve as adjuvants or stabilizers. Furthermore, biochemists have modified proteins to discover amino acid functional groups involved in antibody binding to antigen (see for example, Gudmundsson, et al. Characterisation of residues in antibody binding sites by chemical modification of surface-adsorbed protein combined with enzyme immunoassay. *Journal of Immunological Methods*. Volume 158, Issue 2, 3 February 1993, Pages 215-227). Gudmundsson, et al. teaches the use of several reagents capable of reacting with amino acid functional groups, some of which are in common with bi-functional cross-linking reagents especially reduced sulfhydryl groups, in the investigation of amino acid residues of antibodies important for binding to the cognate antigen. The confirmation of the importance of amino acid functional groups of antibodies was performed using an anti-idiotypic antibody in solution—anti-idiotypic antibodies are antibodies specifically directed to the antigen binding sites of antibodies and are thought to mimic antigenic moieties of antigens. The importance of Gudmundsson, et al. is that

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biochemists have used a finite and known set of reagents to block functional groups of proteins. It would be obvious for a biochemist to use such reagents to modify uncapped crosslinking reagents in the context of cross-linked proteins and use only those that maintained the ability to bind and/or induce specific antibodies. Thus, Applicants' arguments regarding the non-obviousness of combining Mariotti, et al. and Conley, et al. are unconvincing and the rejection of claims 384, 386-387, 392, 394-396 and 402 as obvious over Mariotti, et al., Conley, et al. and Joyce, et al. is **maintained**.

Conclusion

4. No claims are allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on (571)272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Supervisory Patent Examiner, Art Unit 1648

STUART W SNYDER
Examiner
Art Unit 1648

SWS